DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

m3988n

WARNING LETTER
VIA EXPRESS MAIL

JUL 24 2000

Dr. Walter-Gerhard Wrobel
Carl Zeiss Jena Gmbh
Ophthalmic Instruments Division
Tatzenpromenade 1a
07745 Jena, Germany

Dear Dr. Wrobel:

During an inspection of your firm in Jena, Germany, conducted between May 2nd and 5th, 2000, our FDA investigator determined that your firm is manufacturing various surgical laser powered instruments, slit lamps, optical measurement equipment and cameras. These instruments are devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

During the inspection, our investigator determined that your firm had combined two devices, the VISULAS YAG II Plus Intelligent Precision Laser (Photodisruption laser) and the VISULAS 532 Photocoagulation Laser to form a new device, the VISULAS 532 Combination Laser. The VISULAS YAG II Plus Intelligent Precision Laser was cleared for U.S. distribution on December 22, 1993 under K926452. The VISULAS 532 Photocoagulation Laser was cleared for distribution on September 13, 1993 under K925642. During the inspection, Dr. Martin Wiechmann, of your firm, indicated that your firm had not filed an application for a new 510(k) for the VISULAS 532 Combination Laser and that he had filed a "Memo to File" dated April 15, 1998, expressing why your firm believed a new 510(k) application for this device was not necessary.

FDA believes that the VISULAS 532 Combination Laser is misbranded under section 502(o) of the Act, in that a premarket submission was not provided as required by section 510(k) and Title 21, Code of Federal Regulations (CFR), Part 807.81, when significant changes were made that could significantly affect its safety or effectiveness.

Although there is a generic Class II classification for ophthalmic lasers under 21 CFR, part 886.4390, your VISULAS 532 Combination Laser is considered a Class III device until a premarket application is received for it and it is re-classified. Until your firm receives notice from the Center for Devices and Radiological Health clearing this device for commercial distribution, the VISULAS 532 Combination Laser is adulterated within the meaning of section 501(f)(1)(B) of the Act, in that it is a Class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

Our Office of Device Evaluation reviewed your "Memo to File", the inspection report from this recent inspection and labeling materials for all three above devices. FDA believes that this combination device is a new device with new features ([redacted]) and new indications ([redacted]hat require a new 510(k) application.

The recent inspection also found non-conformances to the Quality System Regulations, as specified in Title 21 CFR, Part 820. An FD 483 was issued and annotated with corrections promised to be completed by June 5, 2000. Your firm responded to the 483 in writing on June 1, 2000, and our office reviewed that response as well.

The violations to the Quality Systems Regulation are as follows:

1. 21 CFR 820.184 (d), requires the Device History Record (DHR) to contain or refer to the location of records that demonstrate that the device is manufactured in accordance with the Device Master Record (DMR). Our investigator noted that the wavelength spectrum printout at 200 mWatts (mW) of laser power was not kept nor filed in the device history record. According to the device performance specifications described in your PMA application, [redacted]Your firm uses a spectrum analyzer with the laser power meter to plot the energy units versus the wavelengths. The spectrum analyzer software generates a specific spectral curve and calculates the specific wavelength value at the peak power. However, your firm was not keeping a record of these specific printouts for each DHR to provide proof of readings or to verify the accuracy of the readings.

Your written response indicated that you had revised step 2.13.2 of your test instruction PA319450-7123-001 to require an additional printout of the wavelength spectrum to provide proof of readings and accuracy of the wavelength of the therapy diode. You provided examples of three DHRs that contained this printout. This response appears to be adequate; it will be further verified during your next inspection.

2. The instructions for reading the diode therapy current at the set point temperature are not clear in that they do not indicate which specific current on the supplier data sheet needs to be compared for acceptance. This shows inadequate receiving acceptance activities as required by 21 CFR 820.80(b).

Your written response indicates that you have revised your procedure and corresponding test records. The test instruction now includes a clear reference to the alignment specification with instructions for reading the diode therapy current at the required power levels. It also states that th[redacted]
You provided three DHR data sheets that showed this information correctly filled out. This response appears to be adequate and will be further verified during your next inspection.

3. Also, the procedure for the initial laser diode alignment prior to system installation does not call for recording nor does it identify t[redacted] Three examples of the computer printouts provided during the inspection did not contain the identification of the test operator, acceptance status or identification of the wavelength spectrum. This again appears to show inadequate receiving acceptance activities and documentation as required by 21 CFR 820.80 (b).

Your written response indicates that you have revised step 6.3 of the procedure for the initial laser diode alignment specification to require recording and identifyi[redacted] You provided copies of three DHR that show identification of the test operator, acceptance of the test results, th[redacted] Your response appears to be adequate and will be further verified during your next inspection.

4. The production and testing processes for the VISULAS 690 had not been adequately validated as required by 21 CFR 820.75. The validation test protocol and report do not include nor reference the procedure for the initial laser diode alignment prior to system integration. Neither step 2.14 in the DHR nor step 2.13 of the Test procure indicate how the diode operating temperature is calculated and set, nor do they refer to the laser diode alignment procedure and there is inadequate documentation and explanation of the laser wavelength alignment test results.

Your written response indicates that the process has been revalidated. The validation test protocol was revised to include and reference the procedure for the initial laser diode alignment prior to system integration. A validation report containing corresponding records defined by the alignment specification for three DHRs was included. This response appears to be adequate but will be further verified during your next inspection.

5. Not all sources of quality data are analyzed, reviewed and documented to identify existing and potential causes of nonconforming product and other quality problems as required by 21 CFR 820.100. Specifically [redacted] were recorded on the distribution log were not trended or reviewed for quality indicators (preventive action).

Your firm's written response indicated that general work instruction WI No. OG-QS 12/00 was added to your quality procedures. A specific trend analysis procedure was included to trend and review [redacted] You included a trend analysis assessment that included a graphical representation of the trending data. This appears to be an adequate response and will be further verified during your next inspection.

6. Acceptance criteria were not defined prior to the performance of verification activities for a lens design change in the zoom assembly of the VISULINK PDT adapter as required by 21 CFR 820.30(f). Specifically, three samples of lenses were tested and accepted without definitions for the tolerance of the spot size and output power behind the lens.

Your written response indicated that you have developed a scheme for the verification plan and record that includes the tolerance of the spot size from the original specifications and the output power behind the lens. Engineering Change Request 03/00/13 has been reworked to include these tolerances and your engineers have been retrained in the verification procedure. This response appears to be adequate but will be further verified during the next inspection of your firm.

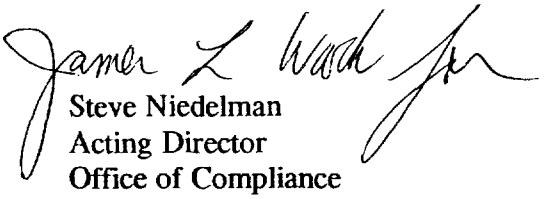
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FD 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct the 510(k) violation. VISULAS 532 Combination Lasers may be detained upon entry into the United States until this violation is corrected.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the attention of Ms. Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch, at the letterhead address. If you have questions concerning this letter you may call her at (301) 594-4613, extension 127, or send a FAX to (301) 594-4638.

Sincerely yours,



Steve Niedelman
Acting Director
Office of Compliance
Center for Devices and Radiological Health